

Krystexxa® (pegloticase) (Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months and will be eligible for renewal.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Krystexxa 8 mg/mL single-use vial: 2 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 16 billable units every 28 days

III. Initial Approval Criteria ¹

Patient is required to meet Site of Service specialty infusion program requirements (refer to the [Dean Health Plan Site of Service Policy](#)).

Submission of medical records (chart notes) related to the medical necessity criteria is **REQUIRED** on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Medical records may be submitted via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patients at higher risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency have been screened and found negative for G6PD before starting Krystexxa; **AND**

- Documentation of baseline serum uric acid level ≥ 7 mg/dL (current lab reports are required for renewal); **AND**

Universal Criteria ^{1,2}

- Therapy will not be given in combination with other urate lowering therapies such as allopurinol, febuxostat, probenecid, lesinurad, etc.; **AND**

Chronic Gout † Φ ¹

- Documented contraindication, intolerance, or clinical failure (i.e., inability to reduce serum uric acid to < 6 mg/dL) during a minimum (3) month trial on previous therapy with maximum tolerated dose of xanthine oxidase inhibitors (e.g., allopurinol or febuxostat) or uricosuric agents (e.g., probenecid, lesinurad, etc.); **AND**
- Used in combination with methotrexate OR as a single agent if methotrexate is contraindicated or not clinically appropriate; **AND**
- Patient has one of the following:
 - 2 or more gout flares per year that were inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), or oral or injectable corticosteroids; **OR**
 - At least one (1) non-resolving subcutaneous tophi; **OR**
 - Evidence of radiographic damage of any modality that is attributable to gout

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment (i.e., reduction of symptoms, reduction of tophi); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include anaphylaxis, infusion reactions, exacerbation of congestive heart failure, hemolytic reactions (including methemoglobinemia and hemolysis), etc.; **AND**
- Documentation of serum uric acid level ≤ 6 mg/dL prior to scheduled infusion

V. Dosage/Administration ¹

| Indication | Dose |
|---|---|
| Chronic Gout | <p>Administer 8 mg as an intravenous infusion every two weeks.</p> <ul style="list-style-type: none">• Patient should receive gout flare prophylaxis with a NSAID or colchicine starting at least 1 week prior to therapy and continuing for at least 6 months• When co-administered with methotrexate, start weekly oral methotrexate 15 mg and folic or folinic acid supplementation at least 4 weeks prior. |
| <i>Note: There is no controlled trial data available on the safety and efficacy of re-treatment with Krystexxa after stopping treatment for longer than 4 weeks. Due to the immunogenicity of Krystexxa, patients receiving re-treatment may be at increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving re-treatment after a drug-free interval should be monitored carefully.</i> | |

VI. Billing Code/Availability Information

HCPCS Code:

- J2507 – Injection, pegloticase, 1 mg; 1 billable unit = 1mg

NDC:

- Krystexxa 8 mg/mL single-use vial: 75987-0080-xx

VII. References

1. Krystexxa [package Insert]. Lake Forest, IL; Horizon Pharma Rheumatology, LLC; July 2022. Accessed February 2023.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care Res (Hoboken). 2020 Jun; 72(6):744-760. Epub 2020 May 11.
3. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. Annals of the Rheumatic Diseases 2017;76:29-42.
4. Qaseem A, Harris RP, Forciea MA, et al. Management of Acute and Recurrent Gout: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. 2017;166(1):58-68.
5. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA. 2011;306(7):711-720. doi:10.1001/jama.2011.1169.
6. Botson J, Tesser J, Bennett R, et al. Pegloticase in Combination With Methotrexate in Patients With Uncontrolled Gout: A Multicenter, Open-label Study (MIRROR). J Rheumatol. 2021 May;48(5):767-774. doi: 10.3899/jrheum.200460. Epub 2020 Sep 15.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|----------|---|
| M1A.00X0 | Idiopathic chronic gout, unspecified site, without tophus (tophi) |
| M1A.00X1 | Idiopathic chronic gout, unspecified site, with tophus (tophi) |
| M1A.0110 | Idiopathic chronic gout, right shoulder, without tophus (tophi) |
| M1A.0111 | Idiopathic chronic gout, right shoulder, with tophus (tophi) |
| M1A.0120 | Idiopathic chronic gout, left shoulder, without tophus (tophi) |
| M1A.0121 | Idiopathic chronic gout, left shoulder, with tophus (tophi) |
| M1A.0190 | Idiopathic chronic gout, unspecified shoulder, without tophus (tophi) |
| M1A.0191 | Idiopathic chronic gout, unspecified shoulder, with tophus (tophi) |
| M1A.0210 | Idiopathic chronic gout, right elbow, without tophus (tophi) |
| M1A.0211 | Idiopathic chronic gout, right elbow, with tophus (tophi) |
| M1A.0220 | Idiopathic chronic gout, left elbow, without tophus (tophi) |
| M1A.0221 | Idiopathic chronic gout, left elbow, with tophus (tophi) |
| M1A.0290 | Idiopathic chronic gout, unspecified elbow, without tophus (tophi) |
| M1A.0291 | Idiopathic chronic gout, unspecified elbow, with tophus (tophi) |
| M1A.0310 | Idiopathic chronic gout, right wrist, without tophus (tophi) |
| M1A.0311 | Idiopathic chronic gout, right wrist, with tophus (tophi) |
| M1A.0320 | Idiopathic chronic gout, left wrist, without tophus (tophi) |
| M1A.0321 | Idiopathic chronic gout, left wrist, with tophus (tophi) |
| M1A.0390 | Idiopathic chronic gout, unspecified wrist, without tophus (tophi) |
| M1A.0391 | Idiopathic chronic gout, unspecified wrist, with tophus (tophi) |
| M1A.0410 | Idiopathic chronic gout, right hand, without tophus (tophi) |
| M1A.0411 | Idiopathic chronic gout, right hand, with tophus (tophi) |
| M1A.0420 | Idiopathic chronic gout, left hand, without tophus (tophi) |
| M1A.0421 | Idiopathic chronic gout, left hand, with tophus (tophi) |
| M1A.0490 | Idiopathic chronic gout, unspecified hand, without tophus (tophi) |
| M1A.0491 | Idiopathic chronic gout, unspecified hand, with tophus (tophi) |
| M1A.0510 | Idiopathic chronic gout, right hip, without tophus (tophi) |
| M1A.0511 | Idiopathic chronic gout, right hip, with tophus (tophi) |
| M1A.0520 | Idiopathic chronic gout, left hip, without tophus (tophi) |
| M1A.0521 | Idiopathic chronic gout, left hip, with tophus (tophi) |
| M1A.0590 | Idiopathic chronic gout, unspecified hip, without tophus (tophi) |
| M1A.0591 | Idiopathic chronic gout, unspecified hip, with tophus (tophi) |
| M1A.0610 | Idiopathic chronic gout, right knee, without tophus (tophi) |
| M1A.0611 | Idiopathic chronic gout, right knee, with tophus (tophi) |
| M1A.0620 | Idiopathic chronic gout, left knee, without tophus (tophi) |
| M1A.0621 | Idiopathic chronic gout, left knee, with tophus (tophi) |
| M1A.0690 | Idiopathic chronic gout, unspecified knee, without tophus (tophi) |

KRYSTEXXA® (pegloticase) Prior Auth Criteria

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| ICD-10 | ICD-10 Description |
|----------|--|
| M1A.0691 | Idiopathic chronic gout, unspecified knee, with tophus (tophi) |
| M1A.0710 | Idiopathic chronic gout, right ankle and foot, without tophus (tophi) |
| M1A.0711 | Idiopathic chronic gout, right ankle and foot, with tophus (tophi) |
| M1A.0720 | Idiopathic chronic gout, left ankle and foot, without tophus (tophi) |
| M1A.0721 | Idiopathic chronic gout, left ankle and foot, with tophus (tophi) |
| M1A.0790 | Idiopathic chronic gout, unspecified ankle and foot, without tophus (tophi) |
| M1A.0791 | Idiopathic chronic gout, unspecified ankle and foot, with tophus (tophi) |
| M1A.08X0 | Idiopathic chronic gout, vertebrae, without tophus (tophi) |
| M1A.08X1 | Idiopathic chronic gout, vertebrae, with tophus (tophi) |
| M1A.09X0 | Idiopathic chronic gout, multiple sites, without tophus (tophi) |
| M1A.09X1 | Idiopathic chronic gout, multiple sites, with tophus (tophi) |
| M1A.30X0 | Chronic gout due to renal impairment, unspecified site, without tophus (tophi) |
| M1A.30X1 | Chronic gout due to renal impairment, unspecified site, with tophus (tophi) |
| M1A.3110 | Chronic gout due to renal impairment, right shoulder, without tophus (tophi) |
| M1A.3111 | Chronic gout due to renal impairment, right shoulder, with tophus (tophi) |
| M1A.3120 | Chronic gout due to renal impairment, left shoulder, without tophus (tophi) |
| M1A.3121 | Chronic gout due to renal impairment, left shoulder, with tophus (tophi) |
| M1A.3190 | Chronic gout due to renal impairment, unspecified shoulder, without tophus (tophi) |
| M1A.3191 | Chronic gout due to renal impairment, unspecified shoulder, with tophus (tophi) |
| M1A.3210 | Chronic gout due to renal impairment, right elbow, without tophus (tophi) |
| M1A.3211 | Chronic gout due to renal impairment, right elbow, with tophus (tophi) |
| M1A.3220 | Chronic gout due to renal impairment, left elbow, without tophus (tophi) |
| M1A.3221 | Chronic gout due to renal impairment, left elbow, with tophus (tophi) |
| M1A.3290 | Chronic gout due to renal impairment, unspecified elbow, without tophus (tophi) |
| M1A.3291 | Chronic gout due to renal impairment, unspecified elbow, with tophus (tophi) |
| M1A.3310 | Chronic gout due to renal impairment, right wrist, without tophus (tophi) |
| M1A.3311 | Chronic gout due to renal impairment, right wrist, with tophus (tophi) |
| M1A.3320 | Chronic gout due to renal impairment, left wrist, without tophus (tophi) |
| M1A.3321 | Chronic gout due to renal impairment, left wrist, with tophus (tophi) |
| M1A.3390 | Chronic gout due to renal impairment, unspecified wrist, without tophus (tophi) |
| M1A.3391 | Chronic gout due to renal impairment, unspecified wrist, with tophus (tophi) |
| M1A.3410 | Chronic gout due to renal impairment, right hand, without tophus (tophi) |
| M1A.3411 | Chronic gout due to renal impairment, right hand, with tophus (tophi) |
| M1A.3420 | Chronic gout due to renal impairment, left hand, without tophus (tophi) |

| ICD-10 | ICD-10 Description |
|----------|--|
| M1A.3421 | Chronic gout due to renal impairment, left hand, with tophus (tophi) |
| M1A.3490 | Chronic gout due to renal impairment, unspecified hand, without tophus (tophi) |
| M1A.3491 | Chronic gout due to renal impairment, unspecified hand, with tophus (tophi) |
| M1A.3510 | Chronic gout due to renal impairment, right hip, without tophus (tophi) |
| M1A.3511 | Chronic gout due to renal impairment, right hip, with tophus (tophi) |
| M1A.3520 | Chronic gout due to renal impairment, left hip, without tophus (tophi) |
| M1A.3521 | Chronic gout due to renal impairment, left hip, with tophus (tophi) |
| M1A.3590 | Chronic gout due to renal impairment, unspecified hip, without tophus (tophi) |
| M1A.3591 | Chronic gout due to renal impairment, unspecified hip, with tophus (tophi) |
| M1A.3610 | Chronic gout due to renal impairment, right knee, without tophus (tophi) |
| M1A.3611 | Chronic gout due to renal impairment, right knee, with tophus (tophi) |
| M1A.3620 | Chronic gout due to renal impairment, left knee, without tophus (tophi) |
| M1A.3621 | Chronic gout due to renal impairment, left knee, with tophus (tophi) |
| M1A.3690 | Chronic gout due to renal impairment, unspecified knee, without tophus (tophi) |
| M1A.3691 | Chronic gout due to renal impairment, unspecified knee, with tophus (tophi) |
| M1A.3710 | Chronic gout due to renal impairment, right ankle and foot, without tophus (tophi) |
| M1A.3711 | Chronic gout due to renal impairment, right ankle and foot, with tophus (tophi) |
| M1A.3720 | Chronic gout due to renal impairment, left ankle and foot, without tophus (tophi) |
| M1A.3721 | Chronic gout due to renal impairment, left ankle and foot, with tophus (tophi) |
| M1A.3790 | Chronic gout due to renal impairment, unspecified ankle and foot, without tophus (tophi) |
| M1A.3791 | Chronic gout due to renal impairment, unspecified ankle and foot, with tophus (tophi) |
| M1A.38X0 | Chronic gout due to renal impairment, vertebrae, without tophus (tophi) |
| M1A.38X1 | Chronic gout due to renal impairment, vertebrae, with tophus (tophi) |
| M1A.39X0 | Chronic gout due to renal impairment, multiple sites, without tophus (tophi) |
| M1A.39X1 | Chronic gout due to renal impairment, multiple sites, with tophus (tophi) |
| M1A.40X0 | Other secondary chronic gout, unspecified site, without tophus (tophi) |
| M1A.40X1 | Other secondary chronic gout, unspecified site, with tophus (tophi) |
| M1A.4110 | Other secondary chronic gout, right shoulder, without tophus (tophi) |
| M1A.4111 | Other secondary chronic gout, right shoulder, with tophus (tophi) |
| M1A.4120 | Other secondary chronic gout, left shoulder, without tophus (tophi) |
| M1A.4121 | Other secondary chronic gout, left shoulder, with tophus (tophi) |
| M1A.4190 | Other secondary chronic gout, unspecified shoulder, without tophus (tophi) |
| M1A.4191 | Other secondary chronic gout, unspecified shoulder, with tophus (tophi) |
| M1A.4210 | Other secondary chronic gout, right elbow, without tophus (tophi) |

| ICD-10 | ICD-10 Description |
|----------|--|
| M1A.4211 | Other secondary chronic gout, right elbow, with tophus (tophi) |
| M1A.4220 | Other secondary chronic gout, left elbow, without tophus (tophi) |
| M1A.4221 | Other secondary chronic gout, left elbow, with tophus (tophi) |
| M1A.4290 | Other secondary chronic gout, unspecified elbow, without tophus (tophi) |
| M1A.4291 | Other secondary chronic gout, unspecified elbow, with tophus (tophi) |
| M1A.4310 | Other secondary chronic gout, right wrist, without tophus (tophi) |
| M1A.4311 | Other secondary chronic gout, right wrist, with tophus (tophi) |
| M1A.4320 | Other secondary chronic gout, left wrist, without tophus (tophi) |
| M1A.4321 | Other secondary chronic gout, left wrist, with tophus (tophi) |
| M1A.4390 | Other secondary chronic gout, unspecified wrist, without tophus (tophi) |
| M1A.4391 | Other secondary chronic gout, unspecified wrist, with tophus (tophi) |
| M1A.4410 | Other secondary chronic gout, right hand, without tophus (tophi) |
| M1A.4411 | Other secondary chronic gout, right hand, with tophus (tophi) |
| M1A.4420 | Other secondary chronic gout, left hand, without tophus (tophi) |
| M1A.4421 | Other secondary chronic gout, left hand, with tophus (tophi) |
| M1A.4490 | Other secondary chronic gout, unspecified hand, without tophus (tophi) |
| M1A.4491 | Other secondary chronic gout, unspecified hand, with tophus (tophi) |
| M1A.4510 | Other secondary chronic gout, right hip, without tophus (tophi) |
| M1A.4511 | Other secondary chronic gout, right hip, with tophus (tophi) |
| M1A.4520 | Other secondary chronic gout, left hip, without tophus (tophi) |
| M1A.4521 | Other secondary chronic gout, left hip, with tophus (tophi) |
| M1A.4590 | Other secondary chronic gout, unspecified hip, without tophus (tophi) |
| M1A.4591 | Other secondary chronic gout, unspecified hip, with tophus (tophi) |
| M1A.4610 | Other secondary chronic gout, right knee, without tophus (tophi) |
| M1A.4611 | Other secondary chronic gout, right knee, with tophus (tophi) |
| M1A.4620 | Other secondary chronic gout, left knee, without tophus (tophi) |
| M1A.4621 | Other secondary chronic gout, left knee, with tophus (tophi) |
| M1A.4690 | Other secondary chronic gout, unspecified knee, without tophus (tophi) |
| M1A.4691 | Other secondary chronic gout, unspecified knee, with tophus (tophi) |
| M1A.4710 | Other secondary chronic gout, right ankle and foot, without tophus (tophi) |
| M1A.4711 | Other secondary chronic gout, right ankle and foot, with tophus (tophi) |
| M1A.4720 | Other secondary chronic gout, left ankle and foot, without tophus (tophi) |
| M1A.4721 | Other secondary chronic gout, left ankle and foot, with tophus (tophi) |
| M1A.4790 | Other secondary chronic gout, unspecified ankle and foot, without tophus (tophi) |
| M1A.4791 | Other secondary chronic gout, unspecified ankle and foot, with tophus (tophi) |

| ICD-10 | ICD-10 Description |
|----------|--|
| M1A.48X0 | Other secondary chronic gout, vertebrae, without tophus (tophi) |
| M1A.48X1 | Other secondary chronic gout, vertebrae, with tophus (tophi) |
| M1A.49X0 | Other secondary chronic gout, multiple sites, without tophus (tophi) |
| M1A.49X1 | Other secondary chronic gout, multiple sites, with tophus (tophi) |
| M1A.9XX0 | Chronic gout, unspecified, without tophus (tophi) |
| M1A.9XX1 | Chronic gout, unspecified, with tophus (tophi) |

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |